## PATENT COOPERATIC TREATY

### **PCT**

### **NOTIFICATION OF ELECTION**

(PCT Rule 61.2)

#### From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents United States Patent and Trademark Office Box PCT Washington, D.C.20231 ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 12 May 2000 (12.05.00)

in its capacity as elected Office

International application No.
PCT/SE99/01354

Applicant's or agent's file reference

PAS-0011.SE

International filing date (day/month/year) 09 August 1999 (09.08.99) Priority date (day/month/year) 19 August 1998 (19.08.98)

**Applicant** 

	ENGVALL, Daniel et al		
1.	The designated Office is hereby notified of its election made:		
	X in the demand filed with the International Preliminary Examining At 17 March 2000 (17.03.00)	uthority on:	
	in a notice effecting later election filed with the International Bureau	ı on:	
		• .	
2.	The election X was was not	· , ; ,	Age is
	made before the expiration of 19 months from the priority date or, where Rule 32.2(b).	Rule 32 appli	ies, within the time limit under
	•		

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Authorized officer

F. Baechier

Telephone No.: (41-22) 338.83.38

Facsimile No.: (41-22) 740.14.35

## PATENT COOPERATION TREATY

	From the INTERNATIONAL BUREAU			
PCT	То:			
NOTIFICATION OF THE RECORDING OF A CHANGE  (PCT Rule 92bis.1 and Administrative Instructions, Section 422)  Date of mailing (day/month/year) 12 May 2000 (12.05.00)	MIKSCHE, Gerhard Conimar AB P.O. Box 2086 S-141 38 Huddinge SUÈDE			
Applicant's or agent's file reference PAS-0011.SE	IMPORTANT NOTIFICATION			
International application No. PCT/SE99/01354	International filing date (day/month/year) 09 August 1999 (09.08.99)			
1. The following indications appeared on record concerning:  the applicant the inventor	the agent the common representative			
Name and Address  MIKSCHE, Gerhard Conimar AB P.O. Box 2086 S-141 02 Huddinge Sweden	State of Nationality   State of Residence			
2. The International Bureau hereby notifies the applicant that the the person				
Name and Address MIKSCHE, Gerhard Conimar AB P.O. Box 2086 S-141 38 Huddinge Sweden	Telephone No. +46-(0)8-608 15 71 Facsimile No. +46-(0)8-689 95 10 Teleprinter No.			
3. Further observations, if necessary:				
4. A copy of this notification has been sent to:  X the receiving Office the International Searching Authority X the International Preliminary Examining Authority	the designated Offices concerned  X the elected Offices concerned  other:			
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer  F. Baechler  Telephone No.: (41-22) 338.83.38			
Facsimile No.: (41-22) 740.14.35	1 gightiong 140. (41.55) 220.02.20			

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## PATENT COOPERATION TREATY

# **PCT**

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WIPO PCT

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTIO	N See Notific	cation of Transmittal of International
PAS-0011.SE		Preliminar	y Examination Report (Form PCT/IPEA/416)
International application No.	International filing date (da	y/month/year)	Priority date (day/month/year)
PCT/SE99/01354	09.08.1999		19.08.1998
International Patent Classification (IPC)	r national classification and	PC <sub>7</sub>	
A 61 F 11/00			
Applicant	7		
Pascal Medical AB et	al		
been amended and are the	of 3 sheets, in anied by ANNEXES, i.e., she basis for this report and/or she of 607 of the Administrative l	acle 36.  Including this coveres of the descripteets containing re	er sheet.  tion, claims and/or drawings which have extifications made before this Authority
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<ol><li>This report contains indications r</li></ol>	elating to the following items	s:	·
I Basis of the report			
II Priority			
	-Ci-iidd to mov	altı impontiva sta	p and industrial applicability
	_	enty, inventive ste	p and industrial applicability
IV Lack of unity of inv	ention		
	under Article 35(2) with regations supporting such staten		ventive step or industrial applicability;
VI Certain documents	rited		
VII Certain defects in the	ne international application		
ا ا	s on the international applica	tion	
Certain observation	, on the international approa		
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Date of submission of the demand	1	Date of completio	n of this report
17.03.2000		01.12.200	0
Name and mailing address of the IPEA/S	SE .	Authorized officer	Г
Patent- och registreringsverket Box 5055	Telex 17978		
S-102 42 STOCKHOLM		Leif Bran	der/Els
Facsimile No. 08-667 72 88		Telephone No. 08	3-782 25 00

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/SE99/01354

I.	Basi	is of the report	
1.	With	regard to the elements of the international application:*	}
	$\boxtimes$	the international application as originally filed	
	一	the description:	
		pages	, as originally filed
		pages	, filed with the demand
	_	pages	, filed with the letter of
		the claims:	, as originally filed
		pages	, as amended (together with any statement) under article 19
		pages	, filed with the letter of
		the drawings:	
	لــا	pages	, as originally filed
		nages	, filed with the demand
		pages	, filed with the letter of
		the sequence listing part of the description:	
		pages	, as originally filed
		pages	, filed with the demand
			, filed with the letter of
2	the in	nternational application was filed, unless otherwise indic se elements were available or furnished to this Authority	in the following language which is:
		the language of a translation furnished for the purpose	
		the language of publication of the international applic	ation (under Rule 48.3(b)).
		or 55.3).	oses of international preliminary examination (under Rules 55.2 and/
3	3. With preli	iminary examination was carried out on the basis of the s	
		contained in the international application in written for	
		filed together with the international application in cor	
		furnished subsequently to this Authority in written fo	
Ì		furnished subsequently to this Authority in computer	readable form.
		- intermedianal application as filed has been furnished	a sequence listing does not go beyond the disclosure in the uter readable form is identical to the written sequence listing has
1	4.	The amendments have resulted in the cancellation of	:
		the description, pages	
		the claims, Nos.	
		the drawings, sheet/fig	
	5.	This report has been established as if (some of) the a beyond the disclosure as filed, as indicated in the Su	mendments had not been made, since they have been considered to go pplemental Box (Rule 70.2 (c)).**
	in	placement sheets which have been furnished to the recei this report as "originally filed" and are annexed to this	iving Office in response to an invitation under Article 14 are referred to report since they do not contain amendments (Rules 70.16
		nd 70.17). By replacement sheet containing such amendments must	be referred to under item I and annexed to this report.

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/SE99/01354

v.	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
	citations and explanations supporting such statement

1.	Statement			
	Novelty (N)	Claims	1-8	YES
	11010113 (11)			NO
		Claims		
				VEC
	Inventive step (IS)	Claims	1-8	YES
		Claims		NO
		•		
	Y 1 med al amaliantilla (IA)	Claims	1 0	YES
	Industrial applicability (IA)		1-8	
		Claims		NO

### 2. Citations and explanations (Rule 70.7)

The invention relates to an apparatus for treating Ménière's disease and is intended to solve the problem of providing a transportable apparatus for ambulant treatment.

The solution according to claim 1 is an inner casing being partially enclosed by an outer casing provided with an opening covered by a removable cover. A storage compartment is disposed between the casings where said storage compartment is surrounding a portion of the inner casing around which a flexible tube provided with an ear plug at its end is disposable in a coiled manner.

In claims 2-8 additional features of the apparatus in claim 1 are disclosed.

US 2652048 A, cited in the International Search Report, shows a transportable apparatus for treatment of ears, but do not disclose an inner casing surrounded by an outer casing in order to provide a storage compartment for a flexible tube in a coiled manner.

Consequently, the invention according to claims 1-8 is considered novel and not obvious to a person skilled in the art.

The invention is considered to be industrially applicable.



# WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



### INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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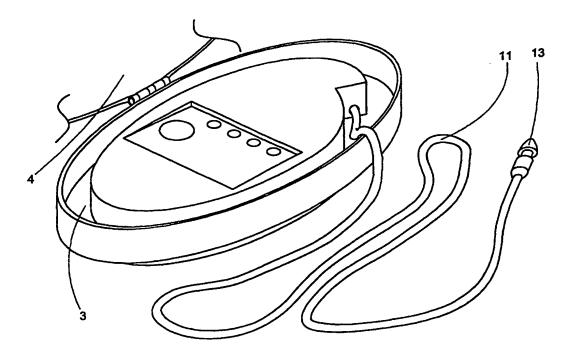
(74) Agent: MIKSCHE, Gerhard; Conimar AB, P.O. Box 2086, S-141 02 Huddinge (SE).

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#### Published

Without international search report and to be republished upon receipt of that report.

(54) Title: TRANSPORTABLE APPARATUS FOR TREATING MENIERE'S DISEASE



(57) Abstract

A transportable apparatus for treating Ménière's disease comprises electronically controlled pressure variation means housed in an inner casing which is partially enclosed by an outer casing provided with an opening covered by a removable cover. A storage compartment is disposed between the casings to receive a flexible tube provided with an ear plug. The flexible tube is connected to the pressure variation means. The storage compartment surrounds a first portion of the inner casing in which the flexible tube can be disposed in a coiled manner.

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WO 00/10484 PCT/SE99/01354

#### TRANSPORTABLE APPARATUS FOR TREATING MÉNIÈRE'S DISEASE

#### FIELD OF THE INVENTION

5

The present invention relates to a transportable apparatus for treating Ménière's disease and similar conditions which affect the pressure balance between the various compartments of the internal ear.

10

#### BACKGROUND OF THE INVENTION

Ménière's disease can be treated by affecting the pressure in the internal ear, in particular the endolymphatic system.

15 A number of apparatus for carrying out this treatment are known in the art. The comprise a pressure generating/control unit to which a flexible tube provided with an ear plug is coupled for conducting pressure pulses to a patient's external ear.

20

WO 83/02556 discloses an apparatus for influencing the hydrodynamic system of the inner of an ear comprising a displaceable diaphragm forming the wall of an air pressure generating chamber, the diaphragm being reciprocally

25 displaceable by means of a crank coupling in a direction away from the chamber against the force of a spring coil.

WO 93/08775 discloses an air pressure generator for the treatment of Ménière's disease by pressure pulses generated 30 by a flexible membrane forming a wall in a pressure generating chamber, the membrane being displaced by actuation means rigidly coupled to the shaft of an electrical motor.

35 WO 97/23178 discloses a device for affecting the hydrodynamic system of the inner ear comprising first means

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for generating a static pressure level and second means for causing a variation of that level in accordance with a predetermined program controlled by a control unit. Each of the first and second means comprise a flexible membrane.

- 5 Also in this known apparatus one half of the reciprocating movement of the diaphragm, the one in which the diaphragm moves towards the pressure generating chamber, is caused by spring means.
- 10 The design of these apparatus is silent about the patient's need for ambulant treatment. To allow the patient to live a life as normal as possible and, in particular, to travel, it should be possible to administer the treatment wherever the patient happens to be. Since such administration implies
- 15 that that it would have to be carried out in the absence of competent health care personnel self-administration should be possible. A transportable apparatus for personal use should also be of a design protecting its delicate parts and the flexible tube/earplug from damage and dirt, and its
- 20 maneuver organs from inadvertent manipulation.

#### OBJECTS OF THE INVENTION

It is an object of the present invention to provide an

25 apparatus for treatment of Ménière's disease and similar conditions by affecting the pressure in the internal ear which is easy to transport by the patient to be used whenever there is a need for treatment, and which takes into account and solves the aforementioned design problems.

30

It is another object of the invention to provide such an apparatus which, in addition, can be operated by the patient without assistance by others.

#### SUMMARY OF THE INVENTION

According to the present invention is provided an apparatus of the aforementioned kind, comprising electronically 5 controlled pressure variation means housed in an inner casing, the inner casing being partially enclosed by an outer casing provided with an opening covered by a removable cover, a storage compartment disposed between the casings, a flexible tube connected to said pressure variation means at 10 its one end and being provided with an ear plug at its other end, the flexible tube being disposable in the storage compartment and removable therefrom with its free end carrying the ear plug for administration of pressure pulses to the external ear of a patient. This solves an important 15 problem since the flexible tube has to be about half a meter long at minimum to allow its ear plug to be fixed to the patient's external ear. If not stored and protected properly it would have a tendency to intertwine and fasten with the ear plug in other gear. This tube length is required for 20 convenient self treatment during which the patient sits at a table while the apparatus rests on the table before him or her.

According to a preferred aspect of the invention the storage 25 compartment surrounds a first portion of the inner casing; preferably the flexible tube is disposed in a coiled manner around that portion. This design provides additional shielding for the most sensitive elements of the apparatus while providing for easy deposition of the tube after a 30 treatment session.

According to a second preferred aspect of the invention the first portion of the inner casing is removable from a second portion of the inner casing. Preferably the second portion

of the inner casing and the outer casing are made from one piece of material. By removing the first portion of the inner casing the electronics and the mechanical parts of the apparatus become accessible for adjustment or repair by a technician without having to disassemble the apparatus. Electronic and mechanical elements of a delicate nature can be disposed in a way that makes them face the first portion. Thereby they are optimally protected by being mounted in the innermost part of the apparatus while remaining easily accessible from outside for repair and testing.

Also preferred is to make the flexible tube pass through an opening in the first portion of the inner casing.

15 According to a third preferred aspect of the invention the first portion of the inner casing is provided with a panel for control of the apparatus by the patient. Thereby an inadvertent start or other manipulation of the apparatus' maneuver organs is prevented.

20

To protect the patient from damage the apparatus of the invention is confined to working pressures not exceeding 30 cm of water column. This is achieved by providing the apparatus with a pressure sensor and to program the 25 microprocessor to open a safety valve once the maximum tolerable pressure is reached.

Advantageously the apparatus of the invention comprises a rechargeable battery in a battery compartment and an electrical connector for connection to a battery eliminator. The battery compartment is advantageously disposed in a way to make it accessible from the rear (bottom) side of the apparatus, that is, the side on which the apparatus stands when in use.

Further preferred features of the present invention are disclosed in the appended claims and a preferred embodiment illustrated in a rough drawing, in which is shown in

- 5 Fig. 1 the apparatus of the invention, in a side view from above, with the casing cover in an open position, and with the flexible tube in a stored (coiled) condition;
- 10 Fig. 2 the apparatus of Fig. 1 and in the same view, with the flexible tube provided with an earplug in an uncoiled position ready for connection to the external ear of a patient;
- 15 Fig. 3 the apparatus of Fig. 1, in a vertical section along its largest diameter, without the flexible tube and with the cover in a closed position.

The apparatus of the invention shown in Figs. 1-3 comprises
20 an inner casing 1 of having about the form of an ellipsoid
delimited by two bases perpendicular to its the axis of
symmetry and thus parallel to each other. One end portion of
the inner casing 1 is surrounded by the wall of an outer
casing 2 which is also ellipsoid in form and shares the axis
25 of symmetry casing 1. The ellipsoid wall of the outer casing
2 is spaced apart from the inner casing 1 to which it is
joined by a bottom flange 3 forming the peripheral part of
what would be its one basis. Thereby an annular space or
groove 6 of elliptic form is formed. Any other suitable
30 form of the apparatus, such as a circular form, would be
equally possible.

The other (topside) basis of outer casing 2 is lacking.

Instead the outer casing 2 is provided with an elliptical

flat cover 4 fastened by a hinge 14 to let it be opened and closed. For most of its circumference, except for a portion in the proximity of the hinge 14, the cover 4 is provided with a rim 15 which overlaps a the outer casing 2 wall when 5 the cover 4 is in a closed position in which it can be releaseably secured to the outer casing 2 (not shown). A simple snap lock (not shown) holds the cover 4 in the closed position; it is moulded into appropriate superimposed (when closed) portions of the inside of rim 15 and the outside of the outer casing 2 wall.

The inner casing 1 contains a pressure generating unit 7 for generating the variations in air pressure to be adduced to the external ear of a patient and, from there, to the patient's internal ear through a tiny tube implanted in the tympanic membrane. The pressure generating unit 7 may comprise a diaphragm pump operated by electrically driven actuating means, such as the assembly disclosed in WO 97/23178. It is only indicated in a general way in Fig. 3.

The pressurized air outlet of the pressure generating unit 7 has the form of a nipple 10 suitable for attaching one end of a flexible plastic tube 11 the other end of which caries an earplug 13 to be inserted into one of the the patient's external ears.

25

The flexible tube 11 extends through a circular opening 8 into the elliptical circumferential groove 6 in which it can be wound up when the apparatus of the invention is not being used. This condition is shown in Fig. 1. The free end 12 of the flexible tube 11 normally carries an earplug 13 which has been omitted in Fig. 1 for reasons of clarity. Though being substantially thicker than the flexible tube 11 the earplug 13 can also be stored in the elliptical groove 6 by

a design making the groove to widen at a portion 9 of the inner casing 1 wall deviating in the direction of the axis of symmetry of the ellipsoid; the opening 8 is arranged in this wall portion 9.

5

- Fig. 2 shows the apparatus of the invention ready for use. The flexible tube 11 is unwound and disposed for most of its length outside of the apparatus of the invention.
- 10 The apparatus in Figs. 1-3 is intended to be put on a horizontal support with its flat underside, the basis pertaining to the portion of the inner casing 1 extending exteriorly of the outer casing 2.
- 15 In addition the inner casing 1 houses an only schematically illustrated electronic control unit 17 including a microprocessor for controlling the generation of the pressure pulses in the pressure generating unit 7. Energy for several treatments can be stored in rechargeable
- 20 batteries 23 disposed in a separate battery compartment 24 accessible from the underside of the apparatus by removing the compartment lock 25. Miniature contacts accessible from outside for recharging the batteries 23 through a battery eliminator are not shown in the Figures; the same is true
- 25 for other electrically operated equipment known in the art, such as a valve for equalizing air pressure in the pressure generating unit 7 and a safety valve.

The top wall 5 of the inner casing 1 is provided with a

30 panel 18 for operation of the apparatus by the patient. The
panel 18 comprises an on/off touch switch 19 and four diode
lights 20 indicating, to the patient: whether the apparatus
is pumping or not; the completion of a treatment session;

that the manual should be consulted; that there is a leakage.

The portion of the inner casing 1 enclosed by the outer

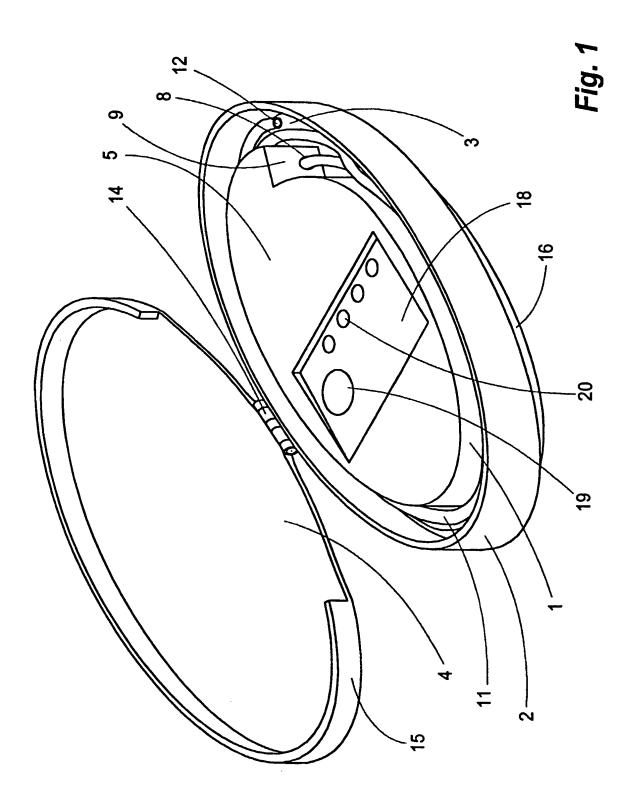
5 casing 2 is mounted by screws 22 to the combination of the not-enclosed portion of 2 and the outer casing 1 which is made in a single piece of a hard polymer material; the same material is used for said mounted portion of the inner casing 2 and the outer casing cover 4. This design provides convenient access to the various parts housed in the inner casing 1.

The apparatus of the invention can be made to a size and a weight which make it convenient to carry. The casings can be 15 manufactured by injection moulding from a variety of polymer materials. A prototype of weighing about 550 g has been tested in patients with good results.

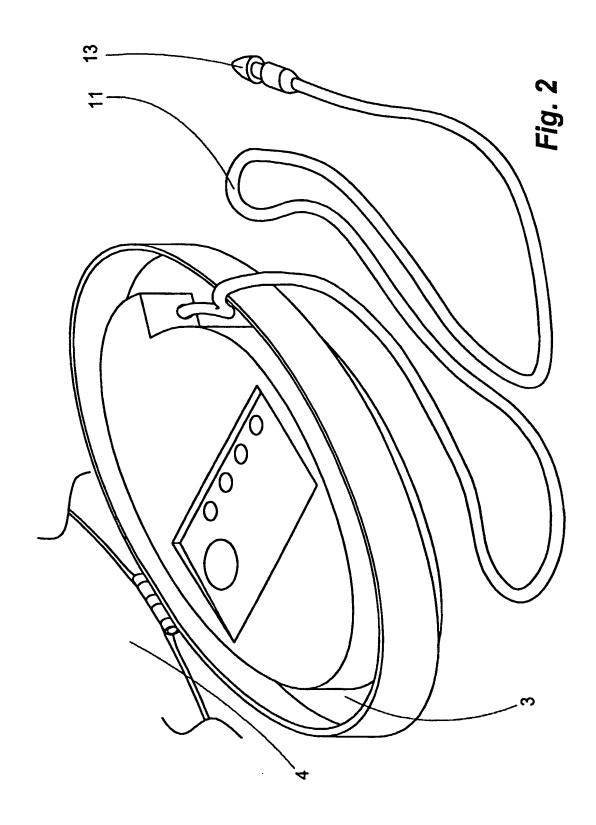
#### Claims

- A transportable apparatus for treating Ménière's 1. disease and similar conditions affecting the pressure 5 balance between the various compartments of the internal ear, comprising electronically controlled pressure variation means housed in an inner casing, the inner casing being partially enclosed by an outer casing provided with an opening covered by a removable cover, a storage compartment 10 disposed between the casings, a flexible tube connected to said pressure variation means at its one end and being provided with an ear plug at its other end, the flexible tube being disposable in the storage compartment and removable therefrom with its free end carrying the ear plug 15 for administration of pressure pulses to the external ear of a patient, said storage compartment surrounding a first portion of the inner casing around which the flexible tube is disposable in a coiled manner.
- 20 2. The apparatus of claim 1, wherein said first portion is removable from a second portion of the inner casing.
- The apparatus of claim 2, wherein said second
   portion of the inner casing and the outer casing are made from one piece of material.
- The apparatus of any of claims 1-3, wherein said first portion of the inner casing is provided with a panel
   for control of the apparatus by the patient.
  - 5. The apparatus of any of claims 1-3, wherein the flexible tube passes through an opening in said first portion of the inner casing.

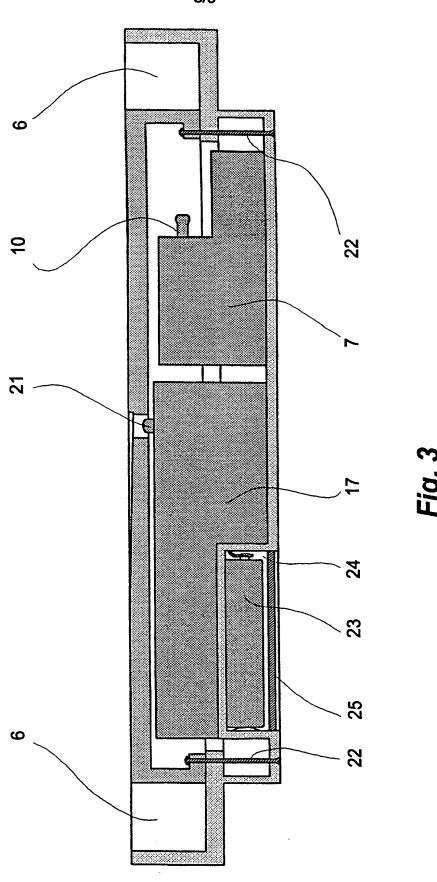
- 6. The apparatus of any of claims 1-5, wherein the pressure pulses do not exceed 30 cm of water column.
- 5 7. The apparatus of any of claims 1-6, comprising a rechargeable battery in a battery compartment and an electrical connector for connection to a battery eliminator.
- 8. The apparatus of any of claims 1-7, wherein said 10 removable cover is hinged to said outer casing.



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# (19) World Intellectual Property Organization International Bureau



## 

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(74) Agent: MIKSCHE, Gerhard; Conimar AB, P.O. Box 2086, S-141 38 Huddinge (SE).

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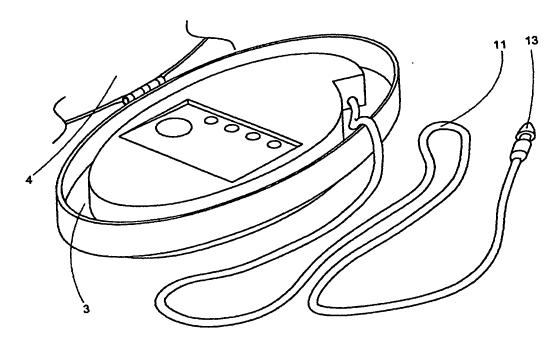
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With international search report.

(88) Date of publication of the international search report: 12 April 2001

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: TRANSPORTABLE APPARATUS FOR TREATING MENIERE'S DISEASE



(57) Abstract: A transportable apparatus for treating Ménière's disease comprises electronically controlled pressure variation means housed in an inner casing which is partially enclosed by an outer casing provided with an opening covered by a removable cover. A storage compartment is disposed between the casings to receive a flexible tube provided with an ear plug. The flexible tube is connected to the pressure variation means. The storage compartment surrounds a first portion of the inner casing in which the flexible tube can be disposed in a coiled manner.

00/10484 A3

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 99/01354

A. CLASSIFICATION OF SUBJECT MATTER		
IPC7: A61F 11/00 According to International Patent Classification (IPC) or to both n	ational classification and IPC	
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed b	y classification symbols)	
IPC7: A61F		
Documentation searched other than minimum documentation to the	e extent that such documents are included in	n the fields searched
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Category* Citation of document, with indication, where ap	propriate, of the relevant passages	Relevant to claim No.
A US 2652048 A (C.F. JOERS), 15 So column 2, line 35 - column	ept 1953 (15.09.53), 3, line 8, figures 1-2	1-8
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